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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/471,040	12/23/1999	ULF TILSTAM	SCH-1615-D1	6934
23599	7590	07/05/2005	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			OWENS JR, HOWARD V	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/471,040	TILSTAM ET AL.	
	Examiner	Art Unit	
	Howard V. Owens	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/1/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to RCE

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 6/1/05 has been entered.

An action on the merits of claims 4-16 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 4-16 are rejected under 35 U.S.C. § 103 as being unpatentable over Montgomery et al., U.S. Patent No. 4,357,324 and Blumbergs et al. (Blumbergs), U.S. 5,110,919.

Claims 4-15 are drawn to Fludarabine-phosphate with a purity ranging from at least 99.5% – 99.85%.

Claim 16 is drawn to an alkaline or earth metal salt of Fludarabine-phosphate.

Montgomery discloses Fludarabine-phosphate or 9-(5-O-phosphate- β -D-arabinofuranosyl)-2-fluoroadenine (claim 4 or columns 2-4). Montgomery isolates the Fludarabine-phosphate from other contaminants via HPLC (col.4, lines 4-6) with subsequent anion exchange chromatography purification. However, Montgomery does not specifically state that the purity of the compound was greater than 99.5%, nor an alkaline or earth metal salt form thereof.

Blumbergs also disclose a crystalline form of fludarabine-phosphate in the earth metal salt form of sodium (see col. 11, lines 20-47).

Although neither Montgomery nor Blumbergs state the purity, one of skill in the art would have a reasonable expectation of success in the attainment of a purity of at least 99.5, post HPLC

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and ion-exchange purification steps. Moreover, one could easily repeat these steps to obtain even higher purity if desired.

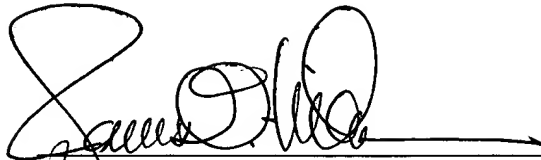
It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to obtain the highest purity available or that commensurate to 99% or better.

A person of ordinary skill in the art would have been motivated to produce Fludarabine-phosphate at a purity of 99.5% or better to achieve the greatest anti-tumor efficacy. One of skill in the art would have had a reasonable expectation of success in the achievement of this purity given that the isolation of the compound had already been demonstrated in the prior art through routine purification techniques.

When claiming a purer form of a known compound, it must be demonstrated that the purified material possess properties and utilities not possessed by the unpurified material, *Ex parte Reed*, 135 USPQ 34,36 (P.O.B.A. 1961). Furthermore, there exists a vast number of decisions holding that where the purification of an old product results in a mere change in its properties, the purified form is unpatentable, *Ex parte Windhaus*, 15 USPQ 45 (POBA 1931); *In re Ridgeway*, 76 F.2d 602, 25 USPQ 202 (CCPA 1935); *In re Merz*, 97 F.2d 599, 38 USPQ 143 (CPA 1938). The claims of the invention do not possess properties and utilities not possessed by the fludara compound disclosed in Montgomery. Applicant has asserted that the highest purity that could be obtained by Montgomery is 99.19%. There is only a .03% difference between that of Montgomery and the claimed purity, which is so insignificant that taking into account experimental error, the claimed composition remains obvious.

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Howard V. Owens
Patent Examiner
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A handwritten signature in black ink, appearing to read "James O. Wilson", written over a horizontal line.

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.